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ABSTRACT

This report was developed to address institutional biosafety committees' implementation of federal guidelines applicable to the environmental release of genetically engineered organisms. These committees are from universities, companies, and other organizations that are using recombinant DNA technology in their laboratories. The committees are responsible for reviewing research proposals using this technology to insure proper containment of recombinant organisms and the safety of laboratory personnel. This report is on the biosafety committees': (1) membership composition; (2) functions and activity levels; (3) implementation of the National Institute of Health guidelines for research involving recombinant DNA molecules; and (4) role in federal regulation of genetically engineered organisms. In addition, the report deals with the involvement of Montana State University's biosafety committee concerning a recent and deliberate release of genetically engineered organisms without prior approval by the committee or by the Environmental Protection Agency. (TW)

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Briefing Report to the Chairman, Committee on Science, Space and Technology, House of Representatives

ED290677

December 1987

BIOTECHNOLOGY

Role of Institutional Biosafety Committees

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Resources, Community, and
Economic Development Division

B-223522

December 14, 1987

The Honorable Robert A. Roe
Chairman, Committee on Science, Space
and Technology
House of Representatives

Dear Mr. Chairman:

The Committee on Science, Space and Technology, asked us to assess institutional biosafety committees' implementation of the federal guidelines applicable to the environmental release of genetically engineered organisms. This request stemmed from questions raised during hearings by your Committee's Subcommittee on Investigations and Oversight regarding whether biosafety committees, as presently constituted, are capable of certifying research for compliance with biotechnology policies of cognizant federal agencies.

Universities, companies, and other organizations using recombinant deoxyribonucleic acid (DNA) technology in laboratories established biosafety committees to implement safety guidelines issued by the National Institutes of Health (NIH) for the conduct of recombinant DNA research. The committees are responsible for reviewing research proposals using this technology to ensure proper containment of recombinant organisms and the protection of laboratory personnel. The NIH guidelines also require that the biosafety committees review deliberate releases of genetically engineered organisms in the environment, although the emphasis of the guidelines is on ensuring adequate containment of recombinant organisms rather than dealing with deliberate release. Now, however, the committees may play an increasing role in reviewing and approving proposed releases as there are more proposals to conduct such experiments.

Your office asked that we focus our attention on four issues: (1) the membership of the biosafety committees, (2) the diversity of their functions and activities, (3) their implementation of the NIH guidelines for research involving recombinant DNA molecules, and (4) their role in overseeing the use of genetically engineered organisms in the environment. To do this, we obtained data from three primary sources (1) biosafety committee membership records on file with NIH's Office of Recombinant DNA Activities in Rockville, Maryland, (2) survey information based on responses to a questionnaire sent to the chairpersons of all public- and

private-sector biosafety committees during May 1987, and (3) documentary information based on interviews conducted in Washington, D.C., with federal officials who are knowledgeable about their agencies' biotechnology policies.

In summary, the results of our survey indicate that:

- There is greater diversity among scientific disciplines than when the institutional biosafety committees were first formed, although the committees are still predominantly composed of members with backgrounds in genetic engineering. Committee members who are not affiliated with the committees' institutions also come predominantly from genetic engineering backgrounds.
- Institutional biosafety committees vary in their functions and activities. Of the committees we surveyed, 60 percent exclusively review recombinant DNA research. Twenty-three percent review recombinant DNA research proposals at least half of their time, but also perform other functions such as overseeing research on infectious diseases, hazardous chemicals, or radioactive materials. The remaining 17 percent devote less than half their time to recombinant DNA research. Those committees that mainly review recombinant DNA research tended to be more active in terms of the frequency of meetings, number of proposals reviewed, and monitoring the research.
- Biosafety committees in both the public- and private-sector organizations have generally complied with the NIH guidelines. Although only about half of the private-sector companies that conduct recombinant DNA research have voluntarily registered a biosafety committee with NIH, those that have registered typically follow the guidelines more closely than their public-sector counterparts. Their compliance is particularly evident in issues related to personnel training, health monitoring, and requiring stricter containment conditions.

Additionally, based on our survey and interviews with federal agency officials, we found that:

- While the relationship between biosafety committees and NIH is well understood, the relationship between some biosafety committees and the federal agencies who are involved in reviewing proposals for the use of genetically engineered organisms in the environment, such as EPA and USDA, has yet to be defined. Chairpersons from these biosafety committees and cognizant agency officials foresee a role for the biosafety committees in this review process, but opinions differ regarding the use of the committee structure by agencies other than NIH, the function of the

committees in the regulatory process, and the present capabilities of the committees to adequately review release proposals.

As agreed with your office, unless you publicly announce its contents earlier, we plan no further distribution of this briefing report until 30 days from the date of this letter. If you have further questions, please contact me at (202) 275-1000. Tabulations of our survey results are given in appendix I. Major contributors to this report are listed in appendix II.

Sincerely yours,

Sarah Frazier Jaggar

Sarah Frazier Jaggar
Associate Director

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Abbreviations

APHIS	Animal and Plant Health Inspection Service
ARS	Agricultural Research Service
BSO	Biological Safety Officer
DNA	Deoxyribonucleic acid
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
GAO	General Accounting Office
IBC	Institutional Biosafety Committee
NIH	National Institutes of Health
NSF	National Science Foundation
ORDA	Office of Recombinant DNA Activities
PI	principal investigator
USDA	Department of Agriculture

Introduction

The Chairman of the House Committee on Science, Space and Technology asked us to assess institutional biosafety committees' implementation of federal guidelines applicable to the environmental release of genetically engineered organisms.

Universities, companies, and other organizations using recombinant DNA[1] technology in their laboratories established biosafety committees to implement the National Institutes of Health (NIH) guidelines for research involving recombinant DNA molecules. The committees are responsible for reviewing research proposals using this technology to ensure proper containment of recombinant organisms and the safety of laboratory personnel. The biosafety committees were not intended to focus primarily on deliberate releases of genetically engineered organisms in the environment. Now, however, they are required to play an increasing role in reviewing and approving proposed releases.

As requested, this report focuses on the biosafety committees'

- membership composition,
- functions and activity levels,
- implementation of the NIH guidelines for research involving recombinant DNA molecules, and
- role in federal regulation of genetically engineered organisms.

In addition, we were asked to report on the involvement of Montana State University's biosafety committee in a recent environmental release incident at that university. The incident involved a university researcher who deliberately released genetically engineered organisms into the environment without prior notification and approval by his local biosafety committee or the Environmental Protection Agency (EPA).

Scope and Methodology

In performing our work, we obtained data from three primary sources: (1) committee membership records on file with the Office of Recombinant DNA Activities (ORDA) in Rockville, Maryland, (2) survey information based on responses to a questionnaire sent to 312 chairpersons of all public- and private-sector biosafety committees registered with ORDA, and (3) documentary information based on interviews conducted in Washington, D.C., with federal officials who are knowledgeable about

[1]DNA (deoxyribonucleic acid) is the genetic material found in all living organisms. Every inherited characteristic has its origin somewhere in the code of each individual's complement of DNA. Recombinant DNA technology involves modifying an organism by breaking up and splicing together DNA fragments from other organisms using molecular biology methods.

their agency's biotechnology policies. We collected and analyzed data from ORDA's files. We also conducted 20 interviews with biosafety committee chairpersons and other authorities to develop and refine a questionnaire that was sent to all chairpersons in May 1987. We then analyzed the responses from 261 chairpersons (84 percent responded), which are tabulated in appendix I. In addition, we interviewed agency officials at the Food and Drug Administration (FDA), EPA, the Department of Agriculture's (USDA) Animal Plant Health Inspection Service and Agricultural Research Service, the Department of Energy (DOE), the Office of Naval Research of the Department of Defense, the National Science Foundation (NSF), ORDA, and officials at Montana State University. We conducted our work between January and July 1987 in accordance with generally accepted governmental auditing standards.

Biosafety Committee Membership Composition

NIH recognized the importance of a broadly based disciplinary representation on institutional biosafety committees when it developed its guidelines. According to a 1976 statement by the NIH Director, "... the biohazards [biosafety] committee must be sufficiently qualified through the experience, expertise, and diversity of its membership to ensure respect for its advice and counsel." In this context, respect was sought from the research community and the general public. Because of a desire for public participation, two public members were to serve on biosafety committees. These public or nonaffiliated members, either local citizens or nonscientists, were to have no affiliation with the institution and therefore may be more likely to raise issues different from those raised by the committee's scientists and may also be more likely to offer contrasting perspectives during proposal review.

Diversity of Membership and Disciplinary Backgrounds

While scientific disciplines dominate biosafety committees' memberships, they are becoming more diversified. For example, in comparison with data from a 1978 study of 30 committees on file with ORDA, these same committees today reflect a decline in members with recombinant DNA expertise, such as microbiologists and biochemists, and an increase of scientists from other related fields. This diversity suggests that the intent of the NIH guidelines to encourage disciplinary diversity of committee members is being met; however, the percentage of members among the three recommended areas of expertise[1] is still heavily weighted toward persons experienced in only the first area, that is, recombinant DNA technology, biological safety, and physical containment.

We found that about 70 percent of the chairpersons expressed little need to change their biosafety committees' composition because they do not foresee a need to review research proposals involving the release of genetically engineered organisms into the environment. However, we also found that the relative level of importance that chairpersons gave to having various backgrounds represented on their committee differed from the actual occurrence of such backgrounds. Figure 2.1 indicates that chairperson preferences for affiliated members with backgrounds in genetic engineering and administration/regulatory affairs come closest to matching their relatively high rate of occurrence on the committees. The most noticeable gaps occur in the areas of physical

[1]The three areas of expertise recommended in the NIH guidelines are (1) recombinant DNA technology, biological safety, and physical containment, (2) institutional commitments and policies, applicable law, standards of professional conduct and practices, community attitudes, and the environment, and (3) laboratory techniques, i.e., laboratory technicians.

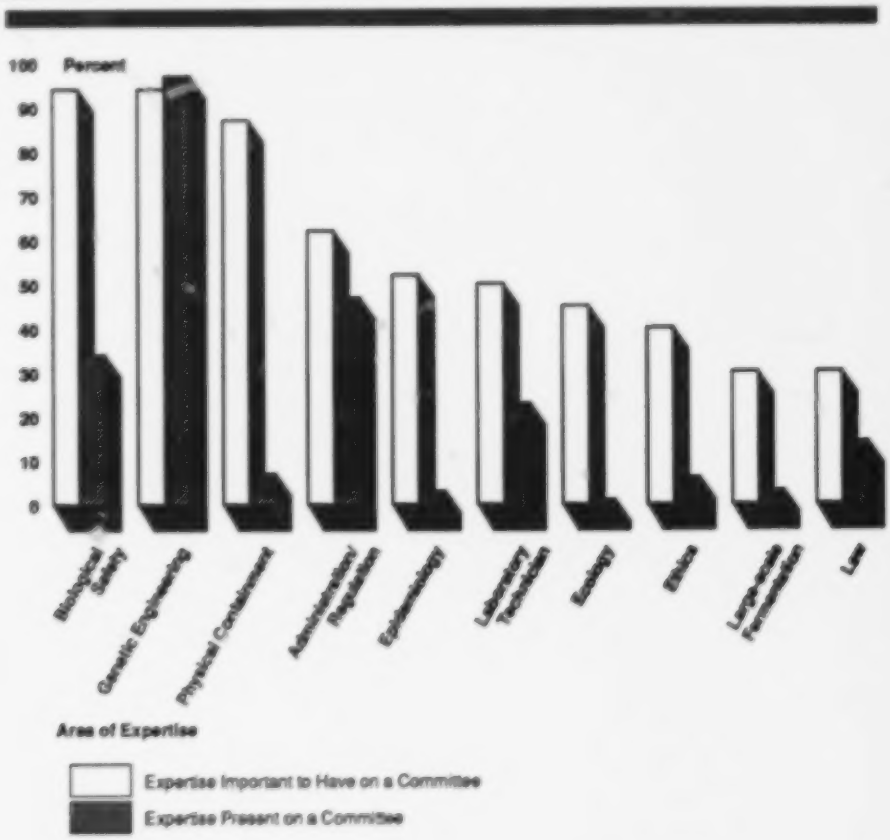
containment, epidemiology, ecology, and large-scale fermentation technology. For example, although 45 percent (116) of the committee chairpersons indicated that having members with backgrounds in ecology was very or moderately important, only 1 committee had an ecologist as a member.

While genetic engineering, the least valued occupational background, is not suggested as an occupation for nonaffiliated members in the NIH guidelines, it has the highest rate of occurrence for these members. Figure 2.2 shows that the closest match between chairperson preferences and actual occurrence of occupations for nonaffiliated members is the medical area of expertise. Occupational backgrounds in public health are perceived as the most important backgrounds for nonaffiliated members, but only about 25 percent of the committees have such members.

Contributions of Nonaffiliated Members

Most biosafety committee chairpersons indicated in our survey that nonaffiliated members have contributed positively to the review process and 76 percent of the chairpersons would keep these members on their committees even if they were not required to do so. Approximately 70 percent of all committee chairpersons responded positively to each of these benefits of having nonaffiliated members: (1) they mention concerns of the community during proposal review, (2) they suggest worthwhile improvements to the review process, and (3) they promote impartial review of colleagues' research proposals. Most chairpersons also did not agree that nonaffiliated members threaten the security of proprietary information (92 percent), that the committee spends too much time explaining technical issues (75 percent), or that they contribute very little to the review process (59 percent).

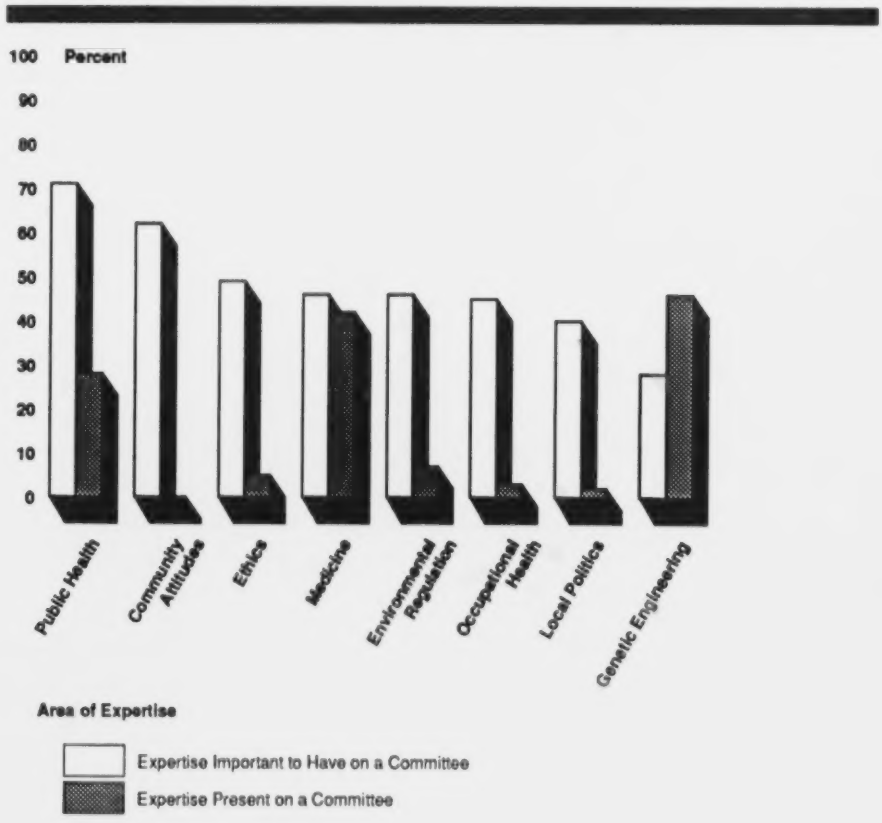
Figure 2.1: Comparison of Chairperson Preferences With Actual Percentage of Affiliated Member Backgrounds on All Committees[a]



[a]The first bar represents the percentage of committee chairpersons who indicated that having an affiliated member with a particular area of expertise on their committees was very or moderately important. The second column represents the percentage of all committees having one or more affiliated members with a particular occupational background.

Opinions differed between public- and private-sector committee chairpersons regarding whether nonaffiliated members sometimes raise scientific issues that would not have been raised otherwise. Forty-two

Figure 2.2: Comparison of Chairperson Preferences With Actual Percentage of Nonaffiliated Member Backgrounds on All Committees[a]



[a]The first bar represents the percentage of committee chairpersons who indicated that having a nonaffiliated member with a particular occupational background on their committees was very or moderately important.

The second column represents the percentage of all committees having one or more nonaffiliated members with a particular occupational background.

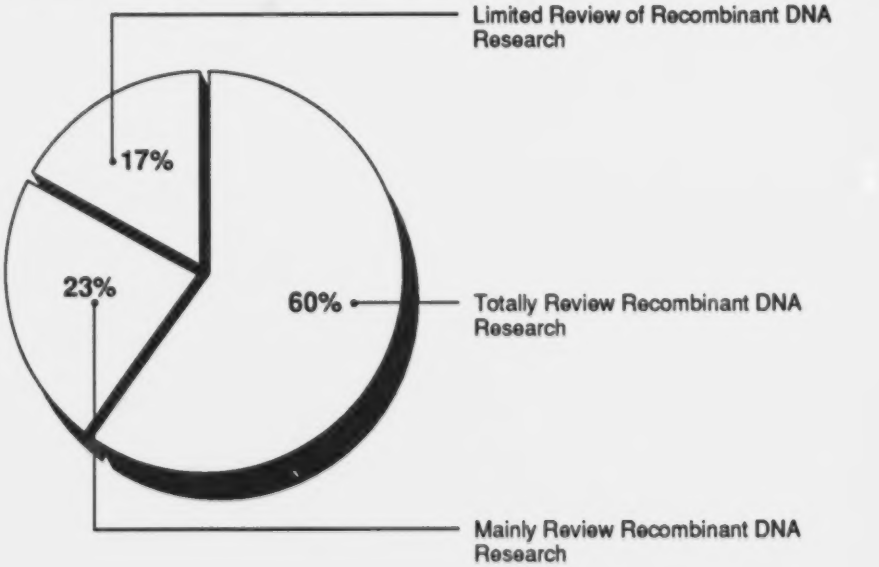
percent of the public- and 63 percent of the private-sector committee chairpersons thought these members raised other issues during the committee meetings. A majority of committee chairpersons (54 percent), however, did not feel that they provide a valuable mechanism for notifying the community about recombinant DNA research activities.

Biosafety Committee Functions and Activity Levels

Because the NIH guidelines are flexible concerning how biosafety committees function, institutions and private companies are able to tailor their biosafety committees' operations to best suit their needs. Consequently, some committees perform more functions for their institutions and companies than just reviewing recombinant DNA research; they are involved in many diverse activities.

For purposes of analysis, we grouped biosafety committees into three functional categories: We characterized the first category as those committees which exclusively review recombinant DNA research (i.e., totally recombinant DNA). The second category is defined as those committees that review recombinant DNA proposals at least half of the time but also perform other functions (i.e., mainly recombinant DNA). These functions may include overseeing research on infectious diseases, hazardous chemicals, or radioactive materials. Committees grouped in the last functional category perform similar functions as committees in the second category, but spend less than half of their time reviewing experimentation using recombinant DNA techniques (i.e., limited recombinant DNA). The proportion of committees in each category is shown in figure 3.3.

Figure 3.1: Grouping of Committees by Functional Category



We also sought to determine whether there were differences in performance associated with these differences in function. We found that the "mainly recombinant DNA" biosafety committees tended to be more active than those committees with other functions. They were more active in terms of the volume of research reviewed, frequency of full committee meetings, and use of subcommittee reviews and input from nonaffiliated members. They also tended to impose stricter containment conditions on the research, modify research proposals more often, and more actively monitor research activities. On the other hand, a prominent characteristic of the "totally recombinant DNA" committees is that they met the least of all the committee types—25 percent of them had not met once in the last 24 months.

Implementation of the NIH Guidelines

Although the safety record of institutions and companies conducting recombinant DNA research is considered exemplary, it is not necessarily a reflection of how well biosafety committees have implemented the NIH guidelines. Many scientists believe that (1) the use of recombinant DNA technology poses little health or safety risk in comparison to working with hazardous chemicals or infectious diseases and (2) it should not be singled out as a technique requiring special scrutiny. Also, much of the experimentation using recombinant DNA techniques is exempt from the NIH guidelines and therefore requires no prior review by the biosafety committees.

In the absence of a significant number of reported compliance violations, a way to judge the performance of the committees in implementing the NIH guidelines is to compare their actual procedures against the guidance given by NIH. We interpreted these guidelines as containing some sections which require specific actions and other sections which suggest discretionary actions that could be taken under certain conditions. Compulsory actions include establishing procedural guidance, meeting membership requirements, reviewing and monitoring activities, and setting containment conditions for certain experiments. Discretionary actions, on the other hand, give institutions and their committees flexibility to tailor other aspects of their biosafety program to the level of risk they deem acceptable for their research activity. Discretionary guidance includes delegating responsibilities for training personnel, increasing containment levels, and instituting a health-monitoring program for laboratory personnel.

By comparing public- and private-sector biosafety committees' adherence to the NIH guidelines, we found that although both generally complied with the compulsory guidelines, the private-sector committees that were registered with ORDA tended to adhere more consistently to the compulsory guidance than the public-sector committees. For example, 73 percent of the private-sector committees had adopted emergency plans, compared with 41 percent of public-sector committees.

Table 4.1 provides the results of our comparison between public- and private-sector committees. Generally, we found that compliance with the compulsory guidelines was addressed by one of three groups: the committee, the biological safety officer (BSO), or the principal investigator (PI). However, the table shows only the frequency of occurrence of the group designated by NIH guidelines.

Table 4.1: Compliance With Compulsory Guidelines by Public- and Private-Sector Committees[a]

Compulsory guidelines	Percentage of compliance: Public-sector	Private-sector
Registration requirements:	n=248[b]	n=64
Submission of member names	100	100
Submission of all vitae	81	86
Updating file yearly	67	77
At least five members	100	100
Two nonaffiliated members	93	98
Review requirements:	n=202	n=56
Likelihood that research activity reported to IBC	65	75
Operational requirements:	n=205	n=56
Initial containment levels determined by PI	49	46
Exemption status determined by PI or committee	93	81
Research monitored by biosafety committee	80	84
Emergency plans adopted by biosafety committee	53	78
Recording of meeting minutes	89 (n=150)	98 (n=50)
BSO appointed[a]	92	100
BSO develops emergency plans[a]	51	66
Lab inspections by BSO[a]	51	66

[a]For the subset of IBCs where a BSO is required, i.e., BL-3 or BL-4 containment levels (n=51 for public and n=9 for private).

[b]The term "n" is defined as the size of the sample.

The private-sector biosafety committees also follow discretionary NIH guidelines more than their public-sector counterparts. In particular, a higher proportion of private committees has reported establishing health surveillance programs, adopted stricter guidelines than required by NIH, and increased research containment conditions beyond requirements. Table 4.2 illustrates the different levels of compliance for public and private committees regarding the discretionary guidelines.

Table 4.2: Compliance With Discretionary Guidelines by Public- and Private-Sector Committees

Discretionary guidelines	Percentage of compliance: Public sector	Percentage of compliance: Private sector
Provide biosafety training	92 (n=205)[a]	98 (n=56)
Health surveillance program	30 (n=204)	66 (n=56)
Encourage open meetings	9 (n=150)	0 (n=50)
Adopt stricter research guidelines	20 (n=204)	50 (n=56)
Increase containment conditions beyond requirements	19 (n=172)	36 (n=47)
Membership composition satisfies all three areas of expertise	24[b] (n=248)	22[b] (n=64)
Voluntary compliance by the private sector	N/A	50[c] (n=64)

[a]The term "n" is defined as the size of the sample.

[b]The present membership composition of both public- and private- sector committees appears to satisfy all recommended areas of expertise in the NIH guidelines with the exception of representation from the laboratory technical staff. Lack of laboratory technicians on the committees significantly reduced the level of performance for this guideline.

[c]We estimated this percentage on the basis of analyzing three separate data sources which contained information on the number of biotechnology companies in the nation and the technologies used in their research and product development.

Biosafety Committees' Role in Federal Regulation of Genetically Engineered Organisms

The institutional biosafety committees were established under the NIH guidelines for the conduct of recombinant DNA research, and the emphasis of those guidelines was on ensuring adequate containment rather than dealing with deliberate releases. Now, however, as there are more proposals for deliberate release experiments, the IBCs are expected to play an increasing role. The increasing range of recombinant DNA research and commercial activities come under the jurisdiction of agencies other than NIH. The policies of federal agencies with responsibilities for overseeing the use of genetically engineered organisms, including those formed by recombinant DNA techniques, were outlined in the June 26, 1986, Federal Register notice "Coordinated Framework for Regulation of Biotechnology."[1] The document contains the regulatory policies of the FDA, EPA, USDA, and Occupational Safety and Health Administration, and the research policies of EPA, USDA, NSF and NIH. For the most part, the agencies contend that existing statutory authorities are adequate to regulate products derived from genetic engineering.

We solicited opinions from federal agency officials and committee chairpersons representing committees that have reviewed environmental release proposals since January 1, 1980, regarding the role of the institutional biosafety committees in federal regulation of genetically engineered organisms. Both groups agreed that the committees should play a role in the review process; however, that role is currently undefined and there is no agreement on the details of what that role should be.

Perspective of Federal Agency Officials

Federal officials we interviewed[2] were generally supportive of the biosafety committees' contributions to the review of recombinant DNA research activities and they foresee a major role for them in assisting federal agencies in their review of research involving the release of genetically engineered organisms into the environment. Although they expressed some doubts about the committees' present capabilities to review such research proposals, they believe that their capabilities can be improved by including additional scientific disciplines on the committees. They also questioned the committees' abilities to enhance public

[1] An evaluation of these policies and procedures for their implementation is contained in a forthcoming GAO report entitled Biotechnology: Managing the Risk of Field Testing Genetically Engineered Organisms.

[2] Federal officials interviewed included those most closely identified with genetic engineering activities, encompassing research and regulation, at their respective agencies. The agencies included the Agriculture Research Service (ARS) and Animal and Plant Health Inspection Service of USDA, EPA, FDA, NIH, NSF, the Office of Naval Research, and DOE.

understanding of related issues when they do not typically deal with the public.

These federal officials commented that biosafety committees should continue exercising their present duties and potentially broaden their role by providing an initial research proposal review or screening function for the benefit of federal agencies. However, they also expressed some concern about jurisdictional problems in this regard. Both the Animal and Plant Health Inspection Service (APHIS) and EPA, for example, expressed interest in developing closer contacts with the committees. But they are concerned about unduly extending their own agencies' regulatory authority and encroaching on NIH's oversight, which historically has included these committees. NIH officials, however, do not consider the jurisdictional issue a serious problem and believe that it can be readily resolved.

Officials at ARS, EPA, and NIH said that the biosafety committees probably or definitely lack the capability to assess environmental release proposals at the present time. Although some officials at APHIS and FDA said that committees probably could perform such reviews, they added that the committees might encounter a problem in this area. Officials attributed the problem to the fact that committees were set up to review laboratory research conducted under contained conditions and that the environmental release issue is a more recent development for which committees have yet to adjust. They suggested that review of a proposal involving a potential environmental release might require the use of consultants as nonvoting committee members or the addition of ecologists as members.

Perspective of Biosafety Committee Chairpersons

Although past biosafety committee involvement in reviewing release proposals is limited, committee chairpersons surveyed believe that, with some modifications to their member compositions, they should continue to assist the agencies in overseeing the use of genetically engineered organisms in the environment. However, 75 percent of the public- and 45 percent of the private-sector chairpersons indicated that they had not reviewed the "Coordinated Framework for Regulation of Biotechnology." This figure includes 12 of the 38 committee chairpersons that anticipate or are uncertain about the involvement of their committees in the review of release proposals in the next 24 months.

Only 13 biosafety committees (6 public- and 7 private-sector committees) out of the 261 committees responding to our survey have reviewed

at least one environmental release proposal. The review of the 22 release proposals submitted to these committees since January 1980 resulted in a variety of outcomes, from rejection of some proposals to approval of others with and without modifications.

A slight majority (7 out of 13 committee chairpersons who have reviewed release proposals) indicated in our survey that they are more comfortable reviewing the assessments of the federal agencies than they are with conducting their environmental impact assessments.[3] This role differs from the role described by federal officials who foresee the committees conducting their own assessment of research proposals prior to agency review.

Twenty-eight of the 38 chairpersons who anticipate or are uncertain about the involvement of their biosafety committees in the review of release proposals[4] in the next 24 months indicated that there is little need to change their membership composition. Twenty-seven chairpersons believe their committees have the requisite expertise available to satisfy their oversight responsibilities. Most of the 11 chairpersons who acknowledged that their groups did not have sufficient expertise planned to change the composition of their committees.

Awareness of Recombinant DNA Research Activities

Regardless of their compliance with NIH guidelines, biosafety committees obviously can only review experiments about which they are informed. Therefore, we sought to determine if any experiments escape the committees' notice. Thirty-five percent of the public-and 26 percent of the private-sector committee chairpersons indicated in our survey that the conduct of nonexempt[5] recombinant DNA research was at least somewhat likely to occur at their institution or company without the awareness of their committee.

[3]Of the 13 chairpersons, only 2 private-sector chairpersons thought that committees should perform their own environmental impact assessments. Seven chairpersons thought that there should be some form of joint review with federal agencies, and one chairperson thought that the federal agencies were not exclusively the most appropriate body to review release proposals.

[4]These 38 committees are most likely to mention agriculture and plant biology as areas of research at their institutions or companies; however, recombinant DNA research in other areas is also conducted in animal drugs and biologics, human drugs, food additives, pesticides, chemicals, and diagnostics.

[5]Nonexempt experiments require biosafety committee review and approval prior to initiation. Nonexempt research now comprises approximately 15 percent of what the NIH guidelines initially covered in 1976.

To further assess this issue, we analyzed data from a 1985 GAO report[6] to identify a knowledge gap between what research activities the chairpersons thought were being conducted at their university and what was actually planned. In 1984, 25 universities had one or more researchers who at least contemplated a release of genetically engineered organisms using recombinant DNA techniques within 1 to 5 years. We found, however, that 16 of the 25 biosafety committee chairpersons representing these universities indicated in our survey that their committee had not reviewed and did not anticipate reviewing any such proposals in the next 24 months. We also found that 2 of the 25 universities have yet to register a biosafety committee with ORDA.

[6]U.S. Department of Agriculture's Biotechnology Research Efforts (GAO/RCED-86-39BR, Oct. 25, 1985). Eighty-seven research projects were identified in which the principal investigators contemplated a release of genetically engineered organisms in 1 to 5 years. We determined that 57 of these projects involved the use of a recombinant DNA technique and thus required institutional biosafety committee review.

The Incident at Montana State University

The recent incident at Montana State University, where a university professor conducted his experimentation without prior approval from the federal government or his local biosafety committee, illustrates a number of problems with (1) university policies regarding the NIH guidelines, (2) committee awareness of research activities, (3) the definition of what constitutes a deliberate release, (4) enforcement of the guidelines, and (5) the relationship between committees and federal agencies. Montana State University is discussed because of recent publicity; however, the problems encountered at this university are similar to what could occur at other universities.

Background

Several newspapers reported details of the Montana State University incident between August and September 1987. The newspaper articles, subsequent biosafety committee reports, and letters between EPA and Montana State University describe a situation that has provided fuel to the critiques of the NIH guidelines and federal regulatory policies toward biotechnology. The incident began in June 1987, when a university researcher, Dr. Gary Strobel, contacted an EPA official about the review requirements pertaining to an experiment he planned to conduct. Although he was told that he needed EPA approval prior to initiating his experiment, Dr. Strobel went ahead with his experiment on June 18, 1987. It was later revealed that he had conducted similar experiments in four states as early as 1983.

Dr. Strobel officially applied for a permit from EPA on June 15 to release Pseudomonas syringae strain 16 H into 14 elm trees on campus in order to determine its effectiveness in combating Dutch elm disease. On July 13, he sent a letter to his local biosafety committee requesting a review of this project, even though it had already started. The committee chairman responded on July 28, advising him of the review requirements in the NIH guidelines. On August 12, the biosafety committee discussed what it should do about this case at an emergency meeting. Subsequently, a subcommittee report was prepared on August 17, addressing the risk of this experiment, followed by an ad-hoc committee hearing on August 28. EPA sent letters to the researcher and the University on August 27 outlining its position and the sanctions it could impose. On September 2, the president of the University issued the researcher a personal reprimand, a day after he voluntarily destroyed the experimental trees.

University Policies Regarding the NIH Guidelines

University officials informed us that a biosafety committee was not officially established at Montana State University until December 1986, even though recombinant DNA research had been taking place at this university for several years. The NIH guidelines delegate responsibility to institutions receiving federal funds for recombinant DNA research to establish a biosafety committee and procedures for the operation of that committee. In interviews with the committee chairman and a university administrator, we were told that, although there were earlier efforts to form a biosafety committee, the administration and some of the researchers were lethargic about setting up a specific committee to implement the NIH guidelines.

Committee Awareness of Research Activities

In our survey, the chairman of the Montana State University biosafety committee, like other committee chairpersons, indicated that he did not anticipate the need for his committee to review any deliberate release proposals within the next 24 months. When interviewed about his response, we were told that at the time, he was not aware that a university researcher was planning a release, nor was he aware that this researcher was using recombinant DNA technology. He told us that prior to instituting some procedural changes to the research notification system at his university, the only way the committee would know about a researcher's intentions was if it were informed directly. In this case, the committee chairman had sent out letters to all departments requesting information on projects using recombinant DNA infectious agents, but this particular researcher had not responded to the request. Dr. Strobel was later quoted in several newspapers as saying that his actions were an act of "civil disobedience," because he did not want the review process to interfere with his field-testing schedule. He later admitted that his actions were wrong, that he acted in haste, and that his earlier remarks about defying regulations were spoken in anger.

Definitional Problems With Deliberate Release

Dr. Strobel stated in a news article that the federal rules are inconsistent, imprecise, and confusing. Members of the biosafety committee recognized that the guidelines and regulations are complex and difficult to interpret, but they also recognized that this researcher should have sought clarification prior to his actions. The committee, however, expressed some doubts about this researcher's knowledge regarding the regulations, stating in its report that this release was neither accidental nor a result of ignorance of federal and university regulations. The researcher, on the other hand, who is the holder of the university's only endowed chair for research, admitted to not being knowledgeable about

the regulations, stating that he did not spend a lot of time reading the Federal Register.

In a subsequent ad-hoc hearing, the biosafety committee found that the NIH guidelines likely did not apply to this case because they did not believe the Pseudomonas syringae strain used contained recombinant DNA. The P. syringae release did, according to the committee, fall under EPA regulations as a genetically engineered microbial pesticide.

Enforcement of the Guidelines

Several groups, including the university's biosafety committee and an industry trade association, called for strict sanctions against this researcher for his actions, but only limited sanctions were imposed. The president of the university personally counseled this researcher about his actions, and EPA sent him a letter stating that he needed prior biosafety committee review and a cosponsor for any new applications he made to the agency. The biosafety committee chairman was disappointed in the level of sanctions. He told us in an interview that if we allow researchers to avoid the guidelines in cases where there is low risk—as recognized in this case—we establish a precedence whereby each researcher will decide what experiments necessitate biosafety committee review. An assistant administrator at EPA admitted in an interview that his agency's sanctions were mild but that nothing else could be done.

Relationship Between the Committee and Federal Agencies

The incident at Montana State University underscores the need for better communication between committees and the federal agencies involved in regulating the use of genetically engineered organisms in the environment. The biosafety committee chairman at Montana State University told us that, although there is a source of information at ORDA regarding changes and interpretations of the NIH guidelines, a similar source at the other federal agencies was not readily available to him. The chairman said that in this case, he was confronted with responding to policies and concerns of four federal agencies—NIH, NSF, USDA, and EPA. When, for example, he called EPA to request that he be put on its mailing list in order to keep apprised of changes in the regulations, he was informed that EPA had no mailing list. Lastly, he informed us that he was aware of EPA's recent statements regarding the important role that EPA foresees for biosafety committees in the federal review process; however, he said that EPA and others he has dealt with have not come forward with guidelines on what they expect the committees to do.

U.S. General Accounting Office Survey of Institutional Biosafety Committees

Introduction

The U.S. House of Representatives' Committee on Science, Space, and Technology asked the General Accounting Office (GAO) to assess the role of Institutional Biosafety Committees (IBCs) in implementing federal guidelines applicable to the environmental release of genetically engineered organisms. In May 1987, we surveyed chairpersons from the 312 public and private sector IBCs that were registered with the National Institutes of Health (NIH) Office of Recombinant DNA Activities (ORDA) at this time. The survey was conducted to help us accurately portray the nature and function of IBCs in our report to the Congress.

This questionnaire was developed to characterize the IBCs by the research they review, their membership, operating procedures, and facilities. A range of answers allowed each question to be easily checked. Space was also provided for the chairpersons to express any additional personal opinions. Because we wanted candid answers from the chairpersons, we provided a pledge of confidentiality.

The results of our survey (based on an 84 percent response rate) are provided for each question.[1] Of the 261 responses received from the 312 biosafety committee chairpersons, 205 are from the public sector and 56 are from the private sector. Data are disaggregated in order to compare responses from chairpersons representing public and private sector committees. The 248 public-sector committees sampled represent institutions that are required to comply with the NIH Guidelines for Research Involving Recombinant DNA Molecules. The 64 private-sector committees sampled, on the other hand, represent companies that generally voluntarily adhere to the NIH Guidelines. In some cases, local governments or federal agencies require companies using recombinant DNA technologies to comply with the Guidance provided by NIH.

Question 1: Is the time and effort spent by members of your IBC reviewing recombinant DNA research proposals too much, too little, or about right, considering the risks of this type of research? (Check one)

Figures in percent

Response Categories	Public	Private
Much too much	2	0
Somewhat too much	8	11
About right	87	82
Small to little	3	7
Total	**100%**	**100%**
Number of respondents	205	56

[1]Since the data have been rounded, column totals may not equal 100 percent.

Section 1: Deliberate Releases

Question 2: In the next 24 months, will your IBC be reviewing any proposals involving the deliberate environmental release of genetically engineered organisms? (Check one)

Figures in percent

Response Categories	Public	Private
Definitely yes	0	9
Probably yes	4	11
Uncertain	8	4
Probably no	43	25
Definitely no	45	52
Total	**100%**	**100%**
Number of respondents	205	56

[a]There are 38 committees (25 public and 13 private) that anticipate reviewing release proposals, including 16 public and 2 private committees that are uncertain.

Question 3: Since January 1, 1980, has your IBC received any proposals that included plans for the deliberate environmental release of genetically engineered organisms? (Check one)

Figures in percent

Response Categories	Public	Private
Yes (GO TO NEXT QUESTION)	3[a]	13[a]
No (SKIP TO 8)	96	87
Unsure (SKIP TO 8)	1	0
Total	**100%**	**100%**
Number of respondents	205	56

[a]These percentages represent 6 public and 7 private-sector committees.

Question 4: Please fill in the approximate number of proposals you received in each of the following time periods for research involving deliberate environmental release of genetically engineered organisms.

Time period	Number public	Number private
Prior to 1/1/84	3	2
1/1/84 - 12/31/85	2	1
1/1/86 - Present	6	8
Total	**11**	**11**

Question 5: Which of the following types of actions has your IBC taken in reviewing research that includes plans for deliberate environmental release of genetically engineered organisms? (Check all that apply)

Response Categories	Number public	Number private
Reject proposal	2	0
Approve with modifications to federal assessment	2	1
Approve with no modifications to federal assessment	1	4
Refer proposal to other review body; no IBC approval/ action	2	0
Other	1	2

Question 6: Which of the following levels of involvement would you prefer for your IBC in regard to assessing the environmental impact of deliberate releases of genetically engineered organisms? (Check one)

Response Categories	Number public	Number private
Assessment of proposals by IBC only (SKIP TO 8)	0	2
IBC reviews assessment by federal agency	5	2
No IBC oversight responsibilities	0	0
Other	1	3

Question 7: At the present time, which of the following do you personally feel is the most appropriate group for reviewing proposals involving the deliberate environmental release of genetically engineered organisms? (Check one)

Response Categories	Number public	Number private
Federal government	6	4
State government	0	0
Local government	0	0
Other	0	

Question 8: Have you reviewed a copy of the federal Coordinated Framework for Regulation of Biotechnology? (Check one)

Figures in percent

Response Categories	Public	Private
Yes	25	55
No	75	45
Total	**100%**	**100%**
Number of respondents	199	56

Question 9: Do you feel that your IBC presently has the expertise needed to properly assess the environmental risk of deliberately released genetically engineered organisms? (Check one)

Figures in percent

Response Categories	Public	Private
Definitely yes	8	13
Probably yes	30	40
Uncertain	17	16
Probably no	36	20
Definitely no	9	13
Total	**100%**	**100%**
Number of respondents	204	56

Question 10: Do you have plans to change the composition of your IBC membership within the next 2 years to acquire expertise to assess the environmental risk of deliberately released genetically engineered organisms? (Check one)

Figures in percent

Response Categories	Public	Private
Yes	4	7
No	17	36
Do not foresee review of such proposals by this IBC	75	54
Other	5	4
Total	**100%**	**100%**
Number of respondents	205	56

Section 2: Duties and Responsibilities

Question 11: For each of the following, check the box for the group that exercises the most responsibility for accomplishing that task at your institution or company.

Figures in percent

Response Categories	IBC or IBC chair		Health & safety unit/ BSO		PI or project manager		Grants/ contracts office		Other[a]		No one designated		Number of respondents	
	Public	Private	Public	Private	Public	Private	Public	Private	Public	Private	Public	Private	Public	Private
Initial determination of containment levels for recombinant DNA molecules	41	32	6	18	49	46	0	0	3	4	0	0	205	56
Determination of whether research is exempt from the NIH Guidelines	70	64	5	20	19	13	2	0	4	4	0	0	205	56
Continuing review of applications and proposals	78	82	10	11	3	5	4	0	2	2	3	0	205	55
Periodic review of laboratories conducting recombinant DNA research	43	49	34	42	11	7	1	0	2	2	9	0	205	55
Providing biosafety training of laboratory personnel	8	5	17	45	62	41	0	0	5	7	8	2	205	56
Developing emergency plans for accidental spills and personnel contamination	17	16	33	46	32	25	0	0	7	11	10	2	205	56

[a]Percentages in the "other" column typically represent those committees that share responsibility for a task with another group.

Question 12: Does your company or institution have a health monitoring program that covers personnel working with recombinant DNA techniques? (Check one)

Figures in percent

Response Categories	Public	Private
Yes (GO TO NEXT QUESTION)	30	66
No (SKIP TO 14)	70	34
Total	**100%**	**100%**
Number of respondents	204	56

Question 13: Does this health monitoring program cover only personnel involved in recombinant DNA research or is it a general program covering other types of research? (Check one)

Figures in percent

Response Categories	Public	Private
Specific program, covers only personnel working with recombinant DNA techniques	10[a]	19[a]
General program, also covers other personnel	90	81
Total	**100%**	**100%**
Number of respondents	59	36

[a]Six institutions and 7 companies have specific programs to monitor health of personnel working with recombinant DNA techniques.

Question 14: Does your institution or company have a designated Biological Safety Officer (BSO)? (Check one)

Figures in percent

Response Categories	Public	Private
Yes	64	60
Yes, but IBC Chair serves as BSO	12	22
No	24	18
Total	**100%**	**100%**
Number of respondents	202	55

Section 3: Your IBC Membership

Question 15: Over a 1 year period, what portion of your IBC membership is typically replaced due to resignations and normal turnover? (Check one)

Figures in percent

Response Categories	Public	Private
Little or none	76	75
Less than half	21	20
About half	2	5
More than half	0	0
All or almost all	0	0
Total	**100%**	**100%**
Number of respondents	198	55

Question 16: Please indicate how important, if at all, having affiliated members[a] with the following backgrounds[b] is for your IBC. (Check one for each type of background)

Figures in percent

	Not very important		Somewhat important		Moderately important		Very important		No basis to judge		Number of respondents	
Response Categories	**Public**	**Private**	**Public**	**Private**	**Public**	**Private**	**Public**	**Private**	**Public**	**Private**	**Public**	**Private**
Genetic engineering	2	4	3	4	10	7	83	86	1	0	202	56
Biological safety	1	2	4	5	15	20	79	73	1	0	202	56
Physical containment	4	0	7	18	31	34	56	48	1	0	202	56
Administration/ Regulation	13	5	28	22	31	40	27	33	2	0	200	55
Ethics	27	27	27	30	24	27	13	9	9	7	203	56
Law	39	30	28	25	17	23	7	14	9	7	202	56
Epidemiology	16	21	26	34	31	32	19	13	8	0	201	56
Ecology	25	21	27	25	27	41	12	11	9	2	198	56
Large-scale fermentation technology	55	20	14	16	12	23	3	41	16	0	202	56
Laboratory technician	30	20	21	18	27	18	16	41	6	4	203	56

[a]Affiliated members are committee members from a company or institution.

[b]Ten percent of the chairpersons suggested other backgrounds that are important for affiliated members.

Question 17: Please indicate how important, if at all, having community members[a] with the following backgrounds is for your IBC. (Check one for each type of background)

Figures in percent

	Not very important		Somewhat important		Moderately important		Very important		No basis to judge		Number of respondents	
	Public	Private	Public	Private	Public	Private	Public	Private	Public	Private	Public	Private
Genetic engineering	49	27	23	27	10	20	11	25	6	2	201	56
Public health	14	5	17	13	30	29	35	52	4	2	202	56
Local politics	33	27	24	27	21	29	15	16	7	2	202	56
Environmental regulations	26	25	29	13	25	45	15	11	7	5	200	55
Medicine	33	14	23	20	25	21	13	39	6	5	202	56
Occupational Health	25	18	30	20	24	32	14	27	8	4	199	56
Community attitudes	15	13	24	16	27	38	29	30	5	4	202	56
Ethics	21	23	27	18	20	29	22	25	9	5	201	56

[a]Community members are committee members that are not financially affiliated with a company or institution.

[b]Ten percent of the chairpersons suggested other backgrounds that are important for community members.

Question 18: If community members were no longer required under the NIH Guidelines would your IBC still retain slots on its committee for community representation? (Check one)

Figures in percent

Response Categories	Public	Private
Definitely yes	34	38
Probably yes	41	43
Uncertain	12	11
Probably no	12	7
Definitely no	0	2
Total	**100%**	**100%**
Number of respondents	203	56

Question 19: Below are some statements describing possible benefits and problems caused by having community members on IBCs. Please indicate how true or not true each statement is for your IBC when you review recombinant DNA research. (Check one for each statement)

Figures in percent

Response Categories	True		Not True		Number of respondents	
	Public	Private	Public	Private	Public	Private
Community members mention concerns of the community during proposal review.	72	82	28	18	201	56
Community members threaten the security of proprietary information.	4	24	96	76	202	55
We spend too much time explaining technical issues to community members.	23	35	77	65	201	56
Community members suggest worthwhile improvements to the review procedures.	67	81	33	19	202	56
Community members promote impartial review of colleagues' research proposals.	65	82	35	18	201	55
Community members sometimes raise scientific issues that would not have been covered otherwise by affiliated members.	42	63	58	37	202	56
The community members on our IBC have contributed very little to the review process.	44	32	56	68	202	56
Community members provide a valuable mechanism for notifying the community about research activities.	47	42	53	58	202	56
It is difficult to find replacements for community members.	58	64	42	36	202	56
It is much more difficult to schedule meetings that include community members.	58	64	42	36	201	56

Section 4: Operating Procedures of Your IBC

Question 20: Is your institution or company required to comply with the NIH Guidelines or are you complying voluntarily? (Check one)

Figures in percent

Response Categories	Public	Private
Required to comply	89	32[b]
Voluntarily comply	11[a]	68
Total	**100%**	**100%**
Number of respondents	204	56

[a]Twenty-two public-sector chairpersons believe that their institution voluntarily complies with the NIH Guidelines.

[b]Eighteen private-sector chairpersons indicated that their company is required to comply with the NIH Guidelines.

Question 21: Does your IBC review biosafety/biohazard issues in addition to those directly associated with recombinant DNA research? For example, answer "yes" if your IBC also determines institution or company protocols for such matters as radiation safety, infectious disease containment, animal care, or use of human subjects.

Figures in percent

Response Categories	Public	Private
Yes	42	32
No (SKIP TO QUESTION 23)	58	68
Total	**100%**	**100%**
Number of respondents	204	56

Question 22: What portion of your IBC's work in the last 12 months involved the discussion of recombinant DNA research? (Check one)

Figures in percent

Response Categories	Public	Private
All or almost all	14	39
More than half	21	39
About half	17	11
Less than half	31	11
Little or none	16	0
Total	**100%**	**100%**
Number of respondents	86	18

Question 23: Has your institution or company established procedures for conducting recombinant DNA research in addition to those specified in the NIH Guidelines? (Check one)

Figures in percent

Response Categories	Public	Private
Yes	21	50
No	79	50
Total	**100%**	**100%**
Number of respondents	204	56

Question 24: Does your institution or company have protocols for physical or biological containment that are stricter than those specified in the NIH Guidelines? (Check one)

Figures in percent

Response Categories	Public	Private
Yes	20	50
No	74	46
Unsure	6	4
Total	**100%**	**100%**
Number of respondents	204	56

Question 25: Does your IBC currently have a requirement that PIs prepare their submissions in terms that are understandable to the non-technical members of the committee? (Check one)

Figures in percent

Response Categories	Public	Private
Yes	26	38
No	69	63
Unsure	4	0
Total	**100%**	**100%**
Number of respondents	204	56

Question 26: Has your IBC adopted emergency plans to cover laboratory accidents related to recombinant DNA research?

Figures in percent

Response Categories	Public	Private
Yes	41	73
No	51	25
Unsure	7	2
Total	**100%**	**100%**
Number of respondents	202	56

Question 27: Which one of the following is the source you use most for notification of changes to the NIH Guidelines pertaining to recombinant DNA research? (Check one)

Figures in percent

Response Categories	Public	Private
Federal Register	54	68
PI or Project Manager	3	4
Recombinant DNA Technical Bulletin	36	18
Other ORDA notifications	1	2
Your institution/company office of regulatory affairs	2	2
Professional publications	3	2
General publications (newspapers, magazines)	0	0
Other (Please describe)	0	5
Total	**100%**	**100%**
Number of respondents	204	56

Question 28: Do you feel that you have enough time to comment on amendments to the NIH Guidelines considering the time between notification and response date? (Check one)

Figures in percent

Response Categories	Public	Private
Definitely yes	10	13
Probably yes	33	39
Uncertain	14	11
Probably no	5	5
Definitely no	3	0
Have not been interested thus far in commenting on amendments	35	32
Total	**100%**	**100%**
Number of respondents	203	56

Question 29: Has your institution or company conducted any research in the last 24 months that involves recombinant DNA molecules? (Check one)

Figures in percent

Response Categories	Public	Private
Yes (GO TO NEXT QUESTION)	98	98
No (SKIP TO 43)	2	2
Total	**100%**	**100%**
Number of respondents	203	55

Question 30: Please indicate whether or not each of the following enforcement mechanisms has been used in the last 24 months by your IBC to encourage researchers to comply with the NIH Guidelines. (Check one for each item)

Figures in percent

Response Categories	Yes		No		Cannot determine		Number of respondents	
	Public	Private	Public	Private	Public	Private	Public	Private
Suspension of IBC approval	5	5	95	91	1	4	192	55
Report violations to internal authority	10	24	89	76	1	0	193	55
Report violations to ORDA	4	4	95	96	1	0	192	55
Laboratory inspections	61	82	37	18	2	0	193	55
Periodic status reports by PI	55	67	45	33	1	0	194	55
Consultations between PI and an IBC member	84	93	13	7	3	0	195	55
Any other actions?	8	9	25	18	67	73	195	55

Question 31: How frequently, if ever, do you designate some of the members of your IBC to review proposals prior to action by the full committee? (Check one)

Figures in percent

Response Categories	Public	Private
All or most of the time	47	44
About half of the time	7	7
Some of the time	13	18
Rarely, if ever	34	31
Total	**100%**	**100%**
Number of respondents	197	55

Question 32: How often, if ever, does your IBC use each of the following methods of decision making to review nonexempt recombinant DNA research proposals?

Figures in percent

Response Categories	None of the time		Less than half of the time		About half of the time		More than half of the time		All of the time		Number of respondents	
	Public	Private	Public	Private	Public	Private	Public	Private	Public	Private	Public	Private
Mail votes	54	57	16	22	8	11	14	9	7	2	167	46
Phone votes	68	63	20	31	4	4	6	2	2	0	158	48
Full committee meetings	12	2	26	10	14	16	16	31	32	41	183	51
Independent decision by IBC chair	56	67	17	22	7	2	13	4	7	4	174	49

Section 5: IBC Meetings and Proposal Review

Please note: Some IBCs cover biosafety matters in addition to recombinant DNA. This section, however, specifically concerns those meetings that include discussions of matters relating directly to recombinant DNA research.

Question 33: How many times has the full committee of your IBC met and discussed recombinant DNA research in the last 24 months? (If no meetings, enter 0 and skip to 38)

Figures in percent

Number of meetings	Public	Private
0	25	9
1	14	15
2	24	24
3	8	15
4	9	18
5	2	0
6	6	2
7	0	2
8	5	11
9	0	4
10	1	0
Over 10	5	2
Total	**100%**	**100%**
Number of respondents	201	65

Question 34: Does your IBC currently announce times and locations of meetings to the general public? (Check one)

Figures in percent

Response Categories	Public	Private
Yes	9	0
No	91	100
Total	**100%**	**100%**
Number of respondents	150	50

Question 35: Over the last 24 months, how frequently, if ever, have members of the general public attended your IBC meetings? (Check one)

Figures in percent

Response Categories	Public	Private
All or most of the time	2	0
About half of the time	1	0
Some of the time	3	0
Rarely	9	2
Never	85	98
Total	**100%**	**100%**
Number of respondents	149	50

Question 36: Over the last 24 months, how frequently, if ever, have your IBC meetings been attended by the principal investigators whose research is being reviewed? (Check one)

Figures in percent

Response Categories	Public	Private
All or most of the time	20	71
About half of the time	7	14
Some of the time	28	6
Rarely, if ever	45	8
Total	**100%**	**100%**
Number of respondents	150	49

Question 37: Does your IBC currently keep formal minutes of all meetings? (Check one)

Figures in percent

Response Categories	Public	Private
Yes	89	98
No	7	2
Other	5	0
Total	**100%**	**100%**
Number of respondents	150	50

Question 38: In the next 12 months, do you think that the number of recombinant DNA proposals your IBC reviews will increase, decrease, or stay about the same? (Check one)

Figures in percent

Response Categories	Public	Private
Increase a lot	3	2
Increase somewhat	41	38
Stay the same	47	51
Decrease somewhat	4	7
Decrease a lot	0	0
No basis to judge	4	2
Total	**100%**	**100%**
Number of respondents	201	55

Question 39: In the last 12 months, approximately how many new and revised research proposals involving recombinant DNA molecules has your IBC reviewed? (Check one)

Figures in percent

Response Categories	Public	Private
None (SKIP TO 43)	13	15
1-5	40	55
6-15	21	25
16-25	9	0
26-50	11	4
Over 50	6	2
Total	**100%**	**100%**
Number of respondents	201	55

Question 40: Considering the recombinant DNA research proposals your IBC reviewed in the last 12 months, for what portion of that research has your IBC required a higher Biosafety Level (BL) containment condition than that specified in the NIH Guidelines? (Check one)

Figures in percent

Response Categories	Public	Private
All or almost all	3	6
More than half	1	9
About half	2	11
Less than half	13	11
Little or none	81	64
Total	**100%**	**100%**
Number of respondents	172	47

Question 41: In the last 24 months, approximately how many times have principal investigators protested the classification of their research under the NIH Guidelines? (If none, enter 0)

Figures in percent

Number of Protests	Public	Private
0	95	94
1	2	4
2	3	2
Total	**100%**	**100%**
Number of respondents	175	47

Question 42: For the recombinant DNA research proposals your IBC review in the last 12 months, please indicate the portion of the time that your IBC disposed of proposals in the following ways.[a](Check one for each type of disposition)

Response Categories	More than half of the time		About half of the time		Some of the time		Rarely if ever		Number of respondents	
	Public	Private	Public	Private	Public	Private	Public	Private	Public	Private
Approval without modification	81	72	10	17	5	9	3	2	172	46
Approval specifying modifications	7	7	15	25	51	48	26	20	164	44
Approval denied	0	0	0	0	7	2	93	98	151	42

[a]Nine percent of the public and 13 percent of the private-sector committee chairpersons suggested other ways that they dispose of the research proposals.

Section 6: Facilities and Operations at Your Company/ Institution

Question 43: Since January 1, 1986, what portion of your recombinant DNA research was conducted under the following biosafety level (BL) containment conditions? If you do not have a facility level or do not use it, please check the appropriate box. (Check one for each type of laboratory)

Figures in percent

	Less than half		About half		More than half		All or almost all		Do not have this level		Not used since 1/1/86		Number of respondents	
	Public	Private	Public	Private	Public	Private	Public	Private	Public	Private	Public	Private	Public	Private
BL 1	12	10	13	4	20	25	47	56	3	6	4	0	195	52
BL 2	49	48	17	8	8	6	9	13	7	12	11	13	181	52
BL 3	29	16	0	0	0	0	1	2	41	63	29	18	169	49
BL 4	1	2	1	0	0	0	0	0	84	94	15	4	164	48

Question 44: Does your institution or company use a large-scale (over 10 liters of culture) research or production facility for research or production activities involving viable organisms that contain recombinant DNA molecules? (Check one)

Figures in percent

Response Categories	Public	Private
Yes (GO TO NEXT QUESTION)	13	56
No (SKIP TO 46)	87	44
Total	**100%**	**100%**
Number of respondents	204	55

Question 45: Since January 1, 1986, what portion of your large-scale (over 10 liters of culture) research or production activities involving recombinant DNA molecules was conducted at the following biosafety level (BL) laboratory facilities? If you do not have a facility level or do not use it, please check the appropriate box under columns 5 and 6. (Check one for each type of laboratory)

Figures in percent

	Less than half		About half		More than half		All or almost all		Do not have this level		Not used since 1/1/86		Number of respondents	
	Public	Private	Public	Private	Public	Private	Public	Private	Public	Private	Public	Private	Public	Private
BL 1 - LS	13	13	4	3	4	10	61	63	4	7	13	3	23	30
BL 2 - LS	19	34	0	3	0	7	29	17	14	14	38	24	21	29
BL 3 - LS	0	4	5	0	0	0	0	4	63	86			19	28

Question 46: Please check the appropriate boxes for each area in which your institution or company conducts research and development or manufactures products that involve recombinant DNA molecules. (Check all that apply for each column)

	R & D		Products	
Response Categories	**Public**	**Private**	**Public**	**Private**
Agriculture/Plant Biology	38	38	0	5
Animal Drugs	14	25	2	5
Animal Biologics	36	38	1	13
Human Drugs/Medical Devices/ Biologics	44	55	3	21
Food/Food Additives	5	21	0	5
Pesticides	9	18	0	2
Chemicals	17	29	1	5
Diagnostics	32	43	3	20
Basic Research	20	5		
Number of respondents	203	56	203	56

[a]Five percent of the public and 4 percent of the private-sector committee chairpersons suggested other research or product areas.

Question 47: In conducting recombinant DNA research, have the principal investigators at your institution or company worked in conjunction with other institutions, sponsors, or manufacturing units either in your community or elsewhere?

Figures in percent

Response Categories	**Public**	**Private**
No, have not collaborated OR	19	15
(CHECK ALL THAT APPLY)		
Yes, in this community	45	35
Yes, in other U.S. communities	71	78
Yes, outside of the U.S.	34	41
Other	2	2
Number of respondents	203	54

Question 48: How likely, if at all, is it that nonexempt, recombinant DNA research could be conducted at your institution or company without prior IBC review?[a] (Check one)

Figures in percent

Response Categories	**Public**	**Private**
Very likely	7	4
Moderately likely	2	2
Somewhat likely	26	20
Not at all likely	65	75
Total	**100%**	**100%**
Number of respondents	202	56

[a]Seventy-one public- and 14 private-sector chairpersons indicated that it is at least somewhat likely that this could occur at their institutions or companies.

Question 49: Which of the following best describes your institution/company? (Check one)

Figures in percent

Response Categories	Public	Private
Private company	1	95
Research institute	15	2
Hospital	2	0
College/University	76	0
Other	5	4
Total	**100%**	**100%**
Number of respondents	203	56

Question 50: Are you currently a principal investigator for research involving recombinant DNA molecules? (Check one)

Figures in percent

Response Categories	Public	Private
Yes	55	32
No	45	68
Total	**100%**	**100%**
Number of respondents	204	56

Question 51: In what month and year did you begin serving as IBC Chair? (Enter two digit equivalent for month such as 04 for April)

Year appointed	Number Public	Number Private
1974	1	0
1975	2	0
1976	3	0
1977	3	0
1978	8	1
1979	10	3
1980	16	0
1981	12	1
1982	14	9
1983	21	5
1984	17	7
1985	40	7
1986	39	17
1987	12	5
Total	**100%**	**100%**
Number of respondents	202	56

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